

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8659

Bartle, J.

August 8 , 2011

Trudy J. Massey ("Ms. Massey" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician Stephen Raskin, M.D., F.A.C.C. Dr. Raskin is no stranger to this litigation. According to the Trust, Dr. Raskin has signed at least 82 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated December 24, 2002, Dr. Raskin attested in Part II of Ms. Massey's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.³ Based on such findings, claimant would

2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Raskin also attested that claimant suffered from New York (continued...)

be entitled to Matrix A-1, Level II benefits in the amount of \$486,424.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Muhammad Yasin, M.D., stated that Ms. Massey had "[m]oderate mitral ... regurgitation." Dr. Yasin, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Irani explained that the "RJA shown includes

3. (...continued)

Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

significant amount of low velocity non regurgitant flow in [left atrium] likely from pulmonary vein inflow."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Massey's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant argued that there was a reasonable medical basis for Dr. Raskin's Green Form representation. In support, claimant submitted a declaration from Dr. Raskin wherein he stated:

Since no hard copy exists of the actual traced or planimetered regurgitant jet area used in the analysis, Dr. Irani has little basis for his assumption that pulmonary venous flow was incorrectly included in the mitral regurgitant area evaluation. My review of the study indeed finds that the December 24, 2002 echocardiogram reveals a central jet *distinct* from any pulmonary venous flow. My review included off-line planimetry of the mitral regurgitant [sic] jet area in the parasternal long-axis view, clearly defining the RJA as a well defined central jet. The mitral regurgitant [sic] color map was assessed in apical and parasternal views and was noted to be best represented in the parasternal long-axis view.

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Massey's claim.

....

Dr. Irani's contention that low flow from the pulmonary veins accounts for an inaccurate mitral regurgitant jet area (RJA) calculation is not supported by my review. In the Massey case a Nyquist limit $>60\text{cm/s}$ may in fact underestimate the degree of mitral regurgitation. Any over tracing of the [mitral regurgitant] jet would typically include random inclusion of light blue low velocity flow and in my analysis I paid particular attention to exclude any entrained flow as well as any possible pulmonary venous flow from the RJA. The [mitral regurgitant] jet boundary was traced with care to avoid including black (no color) areas of the [left atrium]. Any inter-observer variability in [mitral regurgitant] jet tracing did not substantively change the moderate [mitral regurgitation] severity based on the AHP Trust definition.

Moreover, the planimetry of the left atrium (LA) used for the denominator of the RJA/LAA calculation, excluded pulmonary veins and at the mitral annulus a straight line was extrapolated, connecting the attachment point of the leaflets to the valve ring. The left atrial area was the maximal area to avoid foreshortening and possible under-tracing of the [left atrium].

(Internal citations omitted). Dr. Raskin attached several still frames that purportedly demonstrated his findings.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review.

Dr. Irani submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Massey suffered from moderate mitral regurgitation. Specifically, Dr. Irani stated, "I again evaluated Claimant's mitral regurgitant jet area ('RJA') and left

atrial area ('LAA') in the apical views, and again found that Claimant's RJA/LAA ratio does not meet the 20% required for moderate mitral regurgitation. I again concluded that Claimant's mitral regurgitation is mild."

The Trust then issued a final post-audit determination, again denying Ms. Massey's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Massey's claim should be paid. On March 6, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6039 (Mar. 6, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 23, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁶ to review claims after the Trust and

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Massey relies mainly upon the declaration of Dr. Raskin. She also argues that, contrary to the Trust's assertion, Dr. Raskin assessed claimant's mitral regurgitation in both the apical and parasternal views.

In response, the Trust argues that the frames relied upon by Dr. Raskin show that they were traced in the parasternal view, which is inappropriate under the Settlement Agreement. The

Trust also contends that the frames were overtraced to include early systolic and non-regurgitant flow and black pixels. In addition, the Trust submits that a review of multiple frames and loops rather than a single frame is required to assess the level of regurgitation. Finally, the Trust argues that Dr. Raskin did not provide a measurement of the RJA/LAA in the apical view because there was no sustained mitral regurgitant jet.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante concluded that:

A central jet of mitral regurgitation was noted in the parasternal long axis view. I closely reviewed the apical four chamber and apical two chamber views. The cardiac cycles demonstrating the most impressive amount of mitral regurgitation were digitized and the RJA and LAA were measured off-line. Only mild mitral regurgitation was noted. In those cardiac cycles in which the mitral regurgitation appeared most impressive in the apical views, the RJA/LAA ratio was still less than 14%. The RJA/LAA ratio never came close to approaching 20%. The mitral regurgitant jet did not come close to traveling towards the back of the left atrium in the apical views. Two still frames of the supposed mitral regurgitant jet in the apical four chamber view were documented on the tape by the sonographer. These two still frames are not representative of mitral regurgitation and could not be found at all in the real-time evaluation of all the cardiac cycles noted on the tape....

The still frame images submitted by Dr. Raskin were reviewed. The two images demonstrating mitral regurgitation were only

in the parasternal long axis view. There were no submitted still frames of the mitral regurgitant jet in any apical view.

In response to the Technical Advisor Report, claimant again relies on the declaration of Dr. Raskin to argue that there is a reasonable medical basis for his Green Form representation of moderate mitral regurgitation. In addition, claimant submits that Dr. Vigilante incorrectly characterized the extent of Dr. Raskin's review to the parasternal long axis view when Dr. Raskin based his analysis on both the parasternal and apical views.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately respond to Dr. Vigilante's specific determination that "[i]n those cardiac cycles in which the mitral regurgitation appeared most impressive in the apical views, the RJA/LAA ratio was still less than 14%," and that "[t]he RJA/LAA ratio never came close to approaching 20%." Instead, Ms. Massey relies on Dr. Raskin's statement, which does not provide a measurement for the level of her regurgitation, the RJA, or the LAA.

In addition, claimant's reliance on the still frames submitted by Dr. Raskin is misplaced. As we have previously stated, "[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved." PTO No. 6897 at 7 (Jan. 26, 2007) (quoting PTO No. 2640 at 9 (Nov. 14, 2002)). In

any event, Dr. Vigilante reviewed these still frames and determined they were only taken in the parasternal long axis view. As stated above, under the Settlement Agreement, mitral regurgitation must be measured in an apical view. See Settlement Agreement § I.22.⁷

We also reject claimant's reliance on the still frame images documented on the tape by the sonographer. Dr. Vigilante found that these still frames were "not representative of mitral regurgitation and could not be found at all in real-time evaluation of all of the cardiac cycles noted on the tape." As we have held, "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of regurgitation are representative of the level of regurgitation throughout an echocardiogram." PTO No. 6997 at 11 (Feb. 26, 2007). "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." Id.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral

7. We also disagree with claimant that Dr. Vigilante inappropriately characterized Dr. Raskin's analysis. Dr. Vigilante simply stated that the still frame images submitted by Dr. Raskin were only in the parasternal long axis view. Claimant does not dispute this statement.

regurgitation. Therefore, we will affirm the Trust's denial of Ms. Massey's claim for Matrix Benefits.